any time expressed disagreement with the panel's claim construction (Merck's first question), none found fault with the panel's treatment of the district court's fact finding on the merits (Merck's second question), and three questioned the panel's analysis of commercial success (Merck's third question).

REASONS FOR DENYING THE WRIT

I. THE COURT SHOULD NOT CONSIDER MERCK'S "ABOUT" CLAIM CONSTRUCTION ISSUE

A. Merck's First Question is Moot

Merck's proffered construction of claim 23 asserts that "*about* 70 mg, on an alendronic acid basis" does not mean what it says. Instead, according to Merck, it means "*exactly* 70 mg, on an alendronic acid basis." First, correct or not, the argument about the Federal Circuit's interpretation is pointless. The court made clear that although it believed that the district court's construction was erroneous, even under that construction the claims would be invalid:

> It makes no difference to this conclusion whether the court begins with the claim construction set forth by the panel or by the dissent [*i.e.*, by Merck]. In either case the district court erred in finding the '329 patent was not invalid. . . .

(App.16a n.10).

Merck's only response to the Federal Circuit's statement is to say that it was made "defensively" (Pet. 23 n.14), yet Merck's petition fails to articulate how adopting its proposed interpretation could possibly change the result. Indeed, the Federal Circuit's observation is entirely

consistent with Merck's admissions in the case. Merck's principal inventor admitted that persons skilled in the art would have recognized that 70 mg was the appropriate weekly dose because it is seven times the daily dose. Further, Merck conceded that persons skilled in the art would have recognized that the 80 mg dose referred to in the *Lunar News* was chosen only because it represents two tablets of the 40 mg dose that was available in the marketplace for the treatment of Paget's disease. In other words, the difference between exactly 70 mg, which Merck claims is specified in the patent, and 80 mg, specified by the *Lunar News*, is not a distinction that could make Merck's invention unobvious.

Thus, Merck's entire effort is an exercise in futility. This Court should not consider and decide issues that can have no effect on the outcomes of the cases in which they arise. *St. Pierre v. United States*, 319 U.S. 41 (1943) (petition for certiorari that raised "important questions" dismissed because resolution of them would not affect the rights of the litigants).

B. The Federal Circuit Correctly Interpreted the Claims

In construing the claims of the '329 patent, the Federal Circuit followed its own precedent that an interpretation of a term in a patent claim that is contrary to its ordinary meaning must be "clearly expressed" in the patent specification. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 866 (Fed. Cir. 1997). This approach has long been a part of the Federal Circuit's analytical framework, and Merck does not suggest that this Court should overrule it. Merck, however, fails to

address how following that methodology should have yielded a different result.

First, Merck does not dispute that the ordinary meaning of "about 70 mg" is "approximately 70 mg." Merck thus recognizes that it must find in the patent text a clear expression of the construction it proposes, *i.e.*, a construction exactly contrary to that ordinary meaning. As it did in the district court and in the Federal Circuit, Merck mischaracterizes the passage of the patent specification on which it relies to provide that interpretation. In particular, it states that the passage is a "definition" of "about 70 mg." It is not. The key sentence does not say "about 70 mg. . .on an alendronic acid basis. . *means* exactly 70 mg, on an alendronic acid basis." Instead, it states that "about 70 mg. . .on an alendronic acid basis . . . is *calculated based on* 70 mg of alendronic acid." In other words, to normalize the dosage of various possible salts of differing molecular weights, the weight of the compound used is that necessary to provide the same number of molecules as the stated amount of alendronic acid. The statement does not provide a definition of "about 70 mg" of any sort, much less a definition that eviscerates the ordinary meaning of the term. Instead, it states the basis on what it must be calculated: an equivalent amount of the corresponding acid.

This Court's precedents require that a patent claim be construed in the context of the entire patent document. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996) ("standard construction rule. . .[is] that a term can be defined only in a way that comports with the instrument as a whole."); *Bates v. Coe*, 98 U.S. 31, 38 (1878) (patent claim construed with reference to entire document). The Federal Circuit did so, and noted what the district court had ignored: Merck's proposed construction is at odds with the entirety of the rest of the patent text, and, most important,

makes nonsense out of the claims. In particular, in 15 different instances after the occurrence of the purported definition of "about [70] mg," the patent uses the phrase "about [70] mg, on an alendronic acid basis." (App. 14a-15a). If "about [70] mg" by itself meant, as Merck insists, "on an alendronic acid basis," then the latter part of the phrase is redundant. Although a single redundancy might be disregarded as a drafting error, a pattern of 15 raises more than a suspicion that the interpretation that creates the redundancy must be wrong. Similarly, under the district court's interpretation, the claims themselves would contain the same nonsensical redundancy. For example, recast per the district court, claim 23 would read:

> A method for treating osteoporosis in a human comprising orally administering *70 mg, on an alendronic acid basis, of alendronate monosodium salt trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

(Emphasis added). Federal Circuit precedent, whose correctness Merck does not dispute, requires that an interpretation that creates a redundancy in a patent claim is disfavored compared to one that does not. *Electa Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000); *Gen. Am. Transportation Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996). Thus, the Federal Circuit carried out the claim construction task exactly as it should have: it noted the agreed upon "ordinary meaning" of the term, and examined whether the specification clearly expressed a contrary meaning. Noting that the proposed contrary meaning was inconsistent with the patent as a whole, it held that the specification as a whole therefore supported the ordinary meaning.

Merck's argument here is that the Federal Circuit, though charged with interpreting claims "as a matter of law," *Markman*, *supra*, must defer to the district court's construction in this case, even where that construction is inconsistent with the entirety of the remainder of the patent. According to Merck, the district court's construction involved "findings of fact," to which the Federal Circuit should be required to defer.

Although the issue of the deference that should be accorded a district court's subsidiary factual findings made in the context of construing a patent has created interest in the field, this case is not a vehicle for resolving it. First, as discussed above, it is moot. Second, the Federal Circuit claim construction exercise here did not reverse a finding of fact. That is, "about" is not a technical term, and its meaning to those skilled in the art was not the subject of any expert testimony that the district court credited. Indeed, as Merck notes, the district court did not accept Teva's witness's claim construction testimony, and no Merck witness offered any testimony with respect to the meaning of "about 70 mg."[3] Thus, the district court did not weigh the conflicting testimony of experts; it merely rejected the only testimony offered, and relied on its own examination of the patent. The Federal Circuit examined the same text as the district court, but recognized that the

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[3] The principal "testimony" on which Merck relies was Teva's expert's answer, "possibly," to the question posed by Merck's counsel:

> I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated by this?

district court had not done its job – it had ignored aspects that any document construction requires.

The district court's failure to construe the claims with the entire document in mind is not a finding of fact; it is an error of law. Even under a deferential standard, it was freely reviewable. For that reason, this case does not present the issue that Merck suggests should be addressed.

II. THE FEDERAL CIRCUIT GAVE APPROPRIATE DEFERENCE TO THE DISTRICT COURT'S FINDINGS OF FACT UNDER FED. R. CIV. P. 52(a)

Merck's second question, whether the Federal Circuit correctly applied Fed. R. Civ. P. 52(a), presents no issue whose resolution is applicable beyond this case. This Court has already carefully defined the appellate role in reviewing a district court's findings of fact, and Merck's petition does not suggest that any redefinition of that role is necessary. For that reason, the Court should not consider Merck's second question.

In any event, the Federal Circuit correctly applied Rule 52(a). In *Graham v. John Deere Co.*, 381 U.S. 1, 17, this Court defined the three essential factual inquiries in determining whether a patented invention "would have been obvious":

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of skill in the pertinent art resolved.

Here, the parties did not dispute any of these issues. With respect to the scope and content of the prior art, they agreed that persons skilled in the art would have understood that once weekly dosing of alendronate at seven times the daily

dose would be effective, that the *Lunar News* discloses dosing at approximately that level, and that the only reason it refers to "80 mg" instead of "70 mg" was the commercial availability of a 40 mg tablet. They agreed that the *Lunar News* articulates the same motivation for the once-weekly regiment as the '329 patent. They agreed on the definition of a person of ordinary skill in the art. Finally, they agreed that the only difference between the *Lunar News* and the claimed invention, even accepting the district court's claim interpretation, was the precise amount (80 mg vs. 70 mg). The Federal Circuit noted that this difference is insignificant in light of the recognition that 70 mg would have been understood to be the appropriate dose. Thus, with respect to the only relevant factual issues, the parties, the district court and the Federal Circuit agree. There is nothing for this Court to review; the case presents no issue under Rule 52(a).

The key finding that Merck sought, which was the focus of its entire trial presentation, was that persons skilled in the art would have been skeptical of Dr. Mazess's *Lunar News* suggestion notwithstanding its medical and technical merit. The district court made that finding. The Federal Circuit did not reject it; indeed, as Merck is forced to admit, the Federal Circuit accepted it for the purposes of its analysis. (Pet. 25; App. 19a). Moreover, nowhere did the Federal Circuit reject the district court's findings that the *Lunar News* disclosures did not "overcome" medical skepticism, as Merck suggests.

With respect to Dr. Mazess, Merck falsely states that the Federal Circuit "elevated" his expertise "over all others." The court did no such thing. Dr. Mazess never testified at the trial. The court merely pointed out that Dr. Mazess had impressive credentials in the field, a fact that the record overwhelmingly makes clear and that Merck

does not dispute. Moreover, the Federal Circuit rightly noted what Merck also does not dispute: that the *Lunar News* circulated widely within the relevant community, including to Merck's principal inventor, and was read by both experts in the case.

The Federal Circuit's decision did not turn on the relative qualifications and credibility of Dr. Mazess and Merck's expert witness. Instead, it was based on a rejection of Merck's legal theory, *i.e.*, that a prior art publication that is scientifically sound and that subsequent events prove is correct can be nullified based on the credentials of its author. The court recognized that the finding of skepticism, even if supported, is not relevant to the issue of obviousness in this case because, as Merck does not dispute, its patent adds nothing to the *Lunar News* except the Merck name and the academic credentials of its inventors. Under the circumstances, the Federal Circuit held, appropriately, that a second-comer (here, Merck's physician-inventors) cannot obtain a patent on a concept placed in the public domain by someone else solely on the strength of a more prestigious educational experience. As the court stated:

> Indeed, to the extent the district court finds Merck's once-weekly dosing idea non-obvious, it still must explain why Merck and not Dr. Mazess should get credit for the idea.

(App. 21a).

The absurdity of Merck's argument is made plain by its implications. If Merck's inventors had written the *Lunar News* articles, and if Dr. Mazess had obtained the '329 patent, then under Merck's approach the patent would be invalid because the authors' credentials would lend to the publication a *gravitas* that Dr. Mazess's background could not. Similarly, if instead of publishing his idea in the

Lunar News, Dr. Mazess had applied for a patent on it contemporaneously with Merck, then the resulting "interference" proceeding (*see* 35 U.S.C. § 135) would not be decided on the basis of which was the first inventor as the statute requires, but instead on which went to what school.[4] No decision of this or any other court supports Merck's contention that the validity of a patent depends on a comparison of the resumes of the inventor and the prior art author.

The record shows that the Federal Circuit properly applied Rule 52(a). It did not base its decision on a rejection of district court fact findings. Instead, it rejected Merck's groundless legal theory. Recognizing that the determination of obviousness is ultimately a question of law, *Graham*, *supra*, *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1108 (Fed. Cir. 2003), it held that as a matter of law Merck's patent is invalid. This Court should not accept Merck's second question for review.

III. THE FEDERAL CIRCUIT CORRECTLY ANALYZED "COMMERCIAL SUCCESS"

The "commercial success" of an invention is a "secondary consideration" that "may have relevancy" to

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[4] Merck's rationale would require that the Wright brothers be deprived of credit for powered flight, the announcement of which was widely derided, because of their background as bicycle builders. Similarly, Albert Einstein should not be honored for many of his insights, which likewise were at first skeptically received, because he published them while employed not as a university professor, but rather as a mere examiner in the Swiss Patent Office.

whether the invention would have been obvious. *Graham*, *supra*. Whether or not a patented invention is commercially successful, however, the patent is "presumed valid." 35 U.S.C. § 282. Thus, a patentee need not rely on or prove commercial success to prevail against a challenge to the patent.

The rationale for considering commercial success is that it may show that a market demand existed for the patented invention, and that others with an incentive to meet that demand would have done so had the invention been obvious. *See* Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1175 (1964) (*cited in Graham*). *See also Chicago Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452, 459 (7th Cir. 1975), *cert. denied*, 423 U.S. 1091 (1976). As the Federal Circuit stated in this case:

> Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.

(App. 23a). Conversely, if the market is foreclosed to everyone skilled in the art except the patent owner, then the fact that the patentee successfully marketed the invention can say nothing about whether it would have been obvious to others.

Here, the market was foreclosed to all except Merck. Because Merck was the first entity to bring alendronate to market (as a daily dose), it was entitled to a five-year exclusivity, beginning in 1995, for that compound for any pharmaceutical use at any dose. 21 U.S.C. § 355(c)(3)(D)(ii). In addition, Merck had another patent that broadly protected alendronate, excluding everyone else

from the market until 2008.[5] Thus, the commercial success of once-weekly administration of alendronate, even if associated with its advantages compared to the once-daily regimen, is not necessarily attributable to its non-obviousness. Instead, it is just as easily attributable to the fact that all potential competition was foreclosed, so that no one could take up the suggestion of the *Lunar News* for almost 12 years after it was published.

Merck's petition does not dispute the Federal Circuit's stated rationale for considering commercial success. Nor does it dispute the essential fact: that in 1996 no other entity had the economic incentive to attempt to develop a once-weekly alendronate dose, since it would know that it could not market the product for more than a decade. Instead, Merck merely lifts from their contexts quotations from decisions of this and other courts. In none of those cases, however, were the circumstances analogous to those here. In all of them, those skilled in the art were free to compete with the patent owner and were free, if they had the insight, to exploit the patented concept. That they did not do so before the patentee was evidence that the invention was not obvious to them, and therefore would not have been obvious to the hypothetical person of ordinary skill in the art.

Merck complains that the Federal Circuit's decision "discriminates" against improvement patents, stating that a "third party" that patents an improvement can rely on its

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[5] Merck's statement of the issue, which refers only to "improvement patents," ignores the "new chemical entity" exclusivity. It represented an even higher barrier to potential competition than Merck's pre-existing patent because it was not subject to judicial challenge.

commercial success to bolster nonobviousness, but that the owner of the basic patent who likewise patents an improvement cannot. The situation Merck posits, however, will never arise. If, like potential third parties here, Merck's hypothetical third party is foreclosed from competing by the basic patent, it will have no commercial success on which to rely because any attempt to commercialize the improvement will be illegal and will be enjoined. On the other hand, if the improvement is not an infringement of the basic patent, the Federal Circuit's rationale and holding in this case will not apply because competition will not be foreclosed, and the success of any party's improvement invention, including that of the owner of the basic patent, may indeed be evidence that the improvement was not obvious.

The Federal Circuit's ruling may require rigorous analysis of commercial success and the substitution of rationality for the chanting of the "commercial success" mantra. This is a step forward, not a retreat. Commercial success of a patented invention shows that the invention was a good idea. It does not necessarily show that it was unobvious. Carrying an umbrella when the forecast calls for rain is a good idea, but not an unobvious one. Here, the commercial success of once-weekly dosing of alendronate shows that it was a good idea. It was, however, an idea of another, which only Merck could legally exploit. That Merck successfully did so shows nothing more than the fact that only Merck was in a position to do so.

As an afterthought, and in tacit recognition of the force of the Federal Circuit's reasoning, Merck argues that "incentives" in fact existed, referring to the "safe harbor" of 35 U.S.C. § 271(e)(1), which permits otherwise infringing activity if carried out in order to generate data for submission to the FDA, and to speculation about Teva's

activities with respect to alendronate. At trial, however, when it should have addressed the issue with evidence, Merck did not do so. Nothing in the record provides insight into Teva's plans, incentives or the economics of Teva's business model.

Merck's real lament is that even though it had the burden of proof on the issue, it offered no evidence at trial that incentives still existed for those skilled in the art to develop the solutions of the '329 patent notwithstanding the insurmountable barriers to entry created by Merck's patent and statutory exclusivities. Merck in essence asks this Court to write a rule of law that would excuse its failure to prove the necessary facts. This Court should recognize that the Federal Circuit correctly held that under the circumstances of this case, the commercial success of once-weekly alendronate is not probative of the unobviousness of the invention claimed in the '329 patent. For that reason, the Court should not accept Merck's third question for review.

CONCLUSION

Merck's '329 patent is invalid because it claims a concept completely described in the prior art. Merck's petition presents no question worthy of this Court's attention. It should be denied.

September 16, 2005 Respectfully submitted,

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Supreme Court, U.S.
FILED
SEP 2 2 2005
OFFICE OF THE CLERK

No. 05-236

In the Supreme Court of the United States

MERCK & CO., PETITIONER,

v.

TEVA PHARMACEUTICALS USA, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICUS BRIEF OF THE PROCTER & GAMBLE COMPANY SUPPORTING PETITIONER

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September 22, 2005

QUESTION PRESENTED

Amicus asks the Court to grant review on the third question presented in the petition, which amicus casts as follows:

Under 35 U.S.C. § 103(a), a patent may not issue if the differences between the claimed invention and the prior art are such that, at the time the invention was made, the invention would have been "obvious" to a person having ordinary skill in the art to which the invention pertains.

The question presented is whether 35 U.S.C. § 103(a) allows a court to consider the commercial success of an improvement patent in determining whether, at the time the invention was made, the invention would have been "obvious" to a person having ordinary skill in the art.

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INTEREST OF AMICUS[1]

Amicus Procter & Gamble is a large, multi-national company that markets over 300 branded products, including numerous pharmaceutical products. Procter & Gamble holds many patents, the majority of which are improvement patents. Procter & Gamble is a licensee of Merck's U.S. Patent No. 5,994,329. Procter & Gamble has a strong interest in ensuring that the law with respect to improvement patents is clear.

STATEMENT

An "improvement" patent is a patent that builds directly on the teachings of a prior patent. In this case, for example, Merck's U.S. Patent No. 4,621,077 (the " '077 patent") discloses the administration of alendronate as a treatment for osteoporosis. Merck's U.S. Patent No. 5,994,329 (the " '329 patent") is an "improvement" patent that Merck obtained on the prior '077 patent. The '329 patent is an improvement over the '077 patent because it discloses the administration of a higher dose of alendronate on a weekly basis, which increases compliance but does not increase adverse gastrointestinal events.

1. Osteoporosis – or porous bone – "is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures of the hip, spine, and wrist." National Institutes of Health, *Osteoporosis Overview*, at 1 (June 2005), *available at* http://www.osteo.org/inetdocs/r106pi.pdf. The National Institutes of Health have labeled the disease "a major public health threat" for

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[1] Letters of consent have been lodged with the Clerk. No counsel for a party authored any part of this brief. Amicus or its counsel will bear all costs associated with this brief.

more than 44 million Americans and estimate that the disease directly incurs national expenditures of $14 billion a year. *Id.*

The human body is constantly removing old bone and replacing it with new bone. Removal of old bone is called "resorption"; replacement with new bone is called "formation." Until about age 30, bone formation outpaces bone resorption. Then, bone resorption slowly begins to exceed bone formation. Osteoporosis will develop "when bone resorption occurs too quickly or when replacement occurs too slowly." *Id.* at 2.

2. For many years, pharmaceutical manufacturers have sought to develop medicines to treat osteoporosis. Petitioner Merck has centered its work on a compound that inhibits bone resorption. The compound is alendronate, one of a family of drugs known as bisphosphonates. In 1986, Merck obtained the '077 patent on the use of alendronate. Merck markets the compound under the brand name Fosamax.

Merck's Fosamax is one of four prescription drug products available in the United States whose primary indication is for the treatment of osteoporosis. The others are Novartis' Miacalcin, Eli Lily's Evista, and Procter & Gamble's Actonel, which is based upon a bisphosphonate called risedronate. (Together these four drugs are known in the industry as "FAME," for the first letters of the products Fosamax, Actonel, Miacalcin and Evista.) Other pharmaceutical companies were attempting to develop bisphosphonate-based osteoporosis treatments or were marketing other bisphosphonate-based treatments outside the United States.

In 2000, Merck introduced its high-dosage once-weekly Fosamax product, the use of which is claimed in the '329 patent that is the subject of this action. Once-weekly Fosamax was an immediate success. Within six

months of its launch, the once-weekly tablets became the most prescribed drug in the FAME market.

3. In this litigation Teva has argued Merck's invention, once-weekly dosage Fosamax, would have been obvious to one of ordinary skill in the art and that the claims of the '329 patent are, therefore, invalid. At trial, Teva offered evidence of two articles from a prior art publication, *Lunar News*, both of which were entitled "Update: Bisphosphonate." One of the two articles suggested that "[t]he difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration." In addition to mentioning the possibility of once-weekly administrations of alendronate, it also specifically suggested the intravenous administration of another bisphosphonate – ibandronate – as a solution to the difficulties associated with daily dosing of bisphosphonates.

One of Merck's responses to this argument was that the fact of weekly Fosamax's success is relevant to show its claimed invention would not have been obvious. The parties offered evidence relating to this issue, including evidence on what was driving the Fosamax sales. Merck introduced evidence showing that others, including Procter & Gamble, had an opportunity and incentive to develop an improved dosage form. As Judge Farnan noted in his post-trial decision, one of the arguments Teva advanced in response to this evidence was that Merck's commercial success was irrelevant because Merck was the only entity allowed under the '077 patent to market alendronate tablets. Merck responded to Teva's argument by noting that, while it held the '077 patent, its evidence of commercial success was relevant in light of Procter & Gamble's opportunity and incentive to develop a weekly dosing form of Actonel. Judge Farnan focused his analysis on once-weekly Fosamax's "effects on the osteoporosis

market in general" (App. 92a), implicitly rejecting Teva's argument.

4. On appeal, the majority of the court noted:

> Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the *Lunar News* articles.

(App. 23a-24a.) The majority then ruled that:

> Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the *Lunar News* ideas.

(App. 24a.)

The Federal Circuit denied Merck's petition for rehearing *en banc*. In dissent, Judge Lourie, joined by Chief Judge Michel and Judge Newman, argued that rehearing was warranted because the panel majority's ruling effectively held commercial success irrelevant in considering the obviousness of an improvement patent:

> The panel's rule is especially unsound in the context of an improvement patent, as here, because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention.

(App. 38a-39a (Lourie, J., dissenting).)

The dissenters concluded by noting that the panel's opinion "creates" a "confusion in the law." (App. 39a (Lourie, J., dissenting).)

REASONS FOR GRANTING THE WRIT

The Court should grant review because the rule announced by the Federal Circuit threatens to inhibit innovation by making improvement patents more difficult to defend as nonobvious and therefore more risky to pursue. Whether the rule is valid has especially large implications for innovations in medicine in view of the enormous resources devoted by pharmaceutical manufacturers and biotech companies to improving on previously patented medicines. Because the Federal Circuit is the only court of appeals that can decide questions of patent law, and because that court has denied *en banc* review of the panel's decision, only this Court can now resolve the important question of patent law presented.

The commercial success of an invention is normally considered an indication that the invention was not "obvious." The theory is that an invention's commercial success reflects a market demand that, had the invention been obvious, would have led others to try to develop the invention themselves. Here, the Federal Circuit concluded that commercial success has no significance in the case of an improvement patent because no one but the holder of the basic patent could legally have marketed the protected invention.

This rule defines the relevant market too narrowly. In the case of an improvement patent, the relevant market is not necessarily the market for that particular invention. Instead, the relevant market may be the market for inventions of the same general character that would meet the same need. Where, as here, there is evidence that others had the opportunity to develop other ways to skin the same cat, the fact that only the holder of the prior patent could skin the cat with his particular invention does not make the success of his invention irrelevant to its obviousness.

This Court has long recognized that commercial success is a consideration in determining whether an invention merits patent protection: "The utility of the change, as ascertained by its consequences, is the real practical test of the sufficiency of an invention; and since the one cannot exist without the other, the existence of the one may be presumed on proof of the existence of the other." *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876).

Under 35 U.S.C. § 103(a), a patent may be challenged on the ground that it was "obvious" in light of prior art. This Court has held that the commercial success attendant to the introduction of the invention is "relevant" in determining the obviousness of a patent, at least if the success results from the utility of the invention and not some other factor. *Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966). As the Federal Circuit explained in this very case: "Commercial success is relevant [to obviousness] because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." (App. 23a.)

For this reason, the Federal Circuit has long recognized that "the public and commercial response to an invention is a factor to be considered in determining obviousness, and is entitled to fair weight." *Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997). As far as amicus is aware, that court – until now – had consistently *required* district courts to consider evidence of the commercial success of an allegedly obvious innovation. *See, e.g., Ruiz* v. *A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000). The court recognized not only that "[c]ommercial success is * * * a strong factor favoring nonobviousness," *Akzo N.V.* v. *U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed. Cir. 1986), but also that such

objective indicia of nonobviousness as commercial success "may often be the most probative and cogent evidence in the record," *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

The decision of the panel majority – in effect holding that commercial success has no relevance in considering the obviousness *vel non* of an improvement patent – is a sharp break with such precedent, sowing "confusion in the law." (App. 39a (Lourie, J., dissenting).). Because "most inventions represent improvements on some existing article, process, or machine," *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938), the confusion sowed by the panel majority's decision is bound to inhibit innovation. Intervention by this Court is warranted to clarify the law.

The court of appeals held that "[f]inancial success is not significantly probative of [obviousness] in this case because others were legally barred from commercially testing the *Lunar News* ideas." (App. 24a.) However, the *Lunar News* articles spoke of episodic or cyclical administration of bisphosphonates, specifically mentioning not only Merck's alendronate but also Boehringer Manheim's ibandronate-based treatment. It simply does not follow from the existence of Merck's patent on its original alendronate formulation that no one else could legally have developed a safe and effective weekly dosing regimen of a bisphosphonate as a treatment for osteoporosis. The commercial incentive to do so was there; the fact that only Merck did so is an indication that a once-weekly bisphosphonate dosing regimen was not "obvious" at the time Merck obtained the '329 patent.

Indeed, as Merck sought to show at trial, Procter & Gamble itself had incentive and opportunity to develop a once-weekly dosing form of Actonel, a daily bisphosphonate-based osteoporosis treatment. (App. 82a.) Further-

more, the record also indicates that numerous other bisphosphonate-based osteoporosis treatments were being developed and/or marketed outside the United States by other pharmaceutical companies, each of which had the opportunity and incentive to bring to the U.S. market a weekly-dosing treatment.

The point is not that the panel majority failed to give this evidence due weight, but that the panel majority ruled such evidence *irrelevant* when an improvement patent is involved. The Federal Circuit considered it beside the point whether *Lunar News* taught other ways to skin the cat – *i.e.*, other ways to meet the need for a once-weekly bisphosphonate dosing regimen.

But the commercial success achieved by once-weekly Fosamax did not reflect a market need for once-weekly *Fosamax*; it reflected a market need for osteoporosis treatments. Merck's alendronate-based treatment represented but one approach to a problem that many pharmaceutical companies were simultaneously attempting to address in different ways, as the district court recognized in focusing its analysis on once-weekly Fosamax's success in "the osteoporosis market in general," and in finding evidence of commercial success in the fact that Fosamax quickly "became the most prescribed drug in the FAME market." (App. 92a.)

The court of appeals, on the other hand, inappropriately narrowed its field of inquiry by focusing only on Merck's ability, based upon the '077 patent, to preclude others from producing an alendronate-based osteoporosis treatment. This ability, however, did not confer upon Merck a monopoly in the osteoporosis treatment market. Just as Merck was attempting to improve on once-daily Fosamax, its FAME competitors – including Procter & Gamble – were engaged in efforts to improve on their treatments – including Actonel.